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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/259,929	03/01/1999	ANTHONY CERAMI	10162-004-99	5875

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Frederick J Hamble Esq  
712 Kitchawan Road  
Ossining, NY 10562

EXAMINER
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WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 12/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/259929

Applicant(s)

CERAM 1

Examiner

WEBMAN

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☐ Responsive to communication(s) filed on 8/08/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-14, 17-19, 48, 50, 57 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-4, 6-10, 12, 13, 17-19, 50, 57 is/are rejected.
- ☒ Claim(s) 5, 11, 14 is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1617

The election of species requirement over polymers is withdrawn. Claim 48 is withdrawn from prosecution as directed to a non-elected invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 8, 10, 12, 13, 50, 57 rejected under 35 U.S.C. 102(b) as being anticipated by Sturmer et al.

Sturmer et al teach induction of an immune response by implantation of an antigen-impregnated substrate (abstract). A porosity of 0.45 um is disclosed (column 2 lines 61-64). Nitrocellulose is specified (column 2 lines 50-51). As to the claimed container, it is argued that the container and matrix are one and the same.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6 – 10, 12, 13, 50, 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Emery et al.

Emery et al teach priming an immune response by implantation of an implant containing an immunogenic agent (abstract) polylac<sup>†</sup>ide is specified (column 2 line 46). Antigens are disclosed (column 4 lines 61-64). The Statement regarding the claimed container in the previous 102 is incorporated herein.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-10, 12, 13, 17-19, 50, 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emery et al in view of Barr et al.

Emery et al is discussed above. Boosters are additionally disclosed (column 10 lines 58-60). Surgical removal is specified (column 5 lines 1-12).

Barr et al teach an implant that released<sup>s</sup> an active in pulses (abstract).

Antigen is specified (column 3 lines 12-14). Exam<sup>l</sup>ination of a second administration is disclosed (column 3 lines 20-23).

It would have been obvious to one of ordinary skill to use the vehicle of Barr et al in the method of Emery et al to achieve the beneficial effect of one administration.

As to the particular claimed delay and time of removal, such is within the skill of the art In re Boesch 205 USPQ 215 (CCPA 1980). No criticality has been shown.

Claims 8, 10, 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 8, 10 it is unclear as to whether a Markush group is intended or whether applicants intend a copolymer, which is part synthetic and part natural. In claim 19 "Reintroduced into" contradicts the presence of sufficient antigen already in the device for two releases.

Claims 1-4, 6-10, 12, 13, 17-19, 50, 57 are rejected.


Claims 5, 11, 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday to Friday 9 Am 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on (703) 308-0570. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Webman/LR  
November 20, 2002



EDWARD J. WEBMAN  
PATENT EXAMINER  
GROUP 1500